

EXHIBIT E

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING		PAGE OF PAGES 1 32	
2. CONTRACT (Proc. Inst. Ident.) NO. 75F40123C00211				3. EFFECTIVE DATE See Block 20C		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 1269284	
5. ISSUED BY CODE		DAO		6. ADMINISTERED BY (If other than Item 5) CODE		SCD-C	
DHHS/FDA/OAGS/DAO ATTN: Matthew Tran 4041 Powder Mill Road Beltsville MD 20705							
7. NAME AND ADDRESS OF CONTRACTOR (No., street, country, State and ZIP Code) TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK Attn: OLGA CARR 722 W 168TH STREET 4TH FLOOR NEW YORK NY 100323702				8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)			
				9. DISCOUNT FOR PROMPT PAYMENT HHS NET 30P			
				10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN		ITEM	
CODE 135598093		FACILITY CODE					
11. SHIP TO/MARK FOR CODE		WO66		12. PAYMENT WILL BE MADE BY CODE		FDA PAYMENT SVCS	
WHITE OAK CAMPUS, BUILDING 66 The US Food and Drug Administration 10903 New Hampshire Avenue Building 66 Silver Spring MD 20993				FDA PAYMENT SVCS Attn: FDA Vendor payment Team COLE RM8050 8455 Colesville Road Silver Spring MD 20993			
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304 (c) () <input type="checkbox"/> 41 U.S.C. 3304 (a) ()				14. ACCOUNTING AND APPROPRIATION DATA 2023.699R1FQ.25235.C23X2210OCDX545000000			
15A. ITEM NO	15B. SUPPLIES/SERVICES			15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued						
15G. TOTAL AMOUNT OF CONTRACT						\$437,576.00	
16. TABLE OF CONTENTS							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/CONTRACT FORM	1-2	X	I	CONTRACT CLAUSES	25-29
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	3	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	3	X	J	LIST OF ATTACHMENTS	30
X	D	PACKAGING AND MARKING	3	PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	4		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	4-8		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	G	CONTRACT ADMINISTRATION DATA	9-16		M	EVALUATION FACTORS FOR AWARD	
X	H	SPECIAL CONTRACT REQUIREMENTS	16-24				
CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE							
17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return <u>1</u> copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)				18. <input type="checkbox"/> SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)			
19A. NAME AND TITLE OF SIGNER (Type or print) <i>Madhavi Nambiar</i>				20A. NAME OF CONTRACTING OFFICER IAN S. WEISS			
19B. NAME OF CONTRACTOR TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW BY _____ (Signature of person authorized to sign)			19C. DATE SIGNED 9/28/2023	20B. UNITED STATES OF AMERICA BY <i>[Signature]</i> (Signature)		20C. DATE SIGNED Digitally signed by Ian S. Weiss -S Date: 2023.09.28 10:59:56 -04'00'	

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75F40123C00211	PAGE	OF
		2	32

NAME OF OFFEROR OR CONTRACTOR

TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 13-5598093 UEI: QHF5ZZ114M72 BAA FY23C3DWP3 - Health and Neurodevelopmental Outcomes in Infants at Risk for (NOWS) Effects of timing and Duration of (POE) and Postnatal Management with (ESC) Delivery: 09/29/2024 Appr. Yr.: 2023 CAN: 699R1FQ Object Class: 25235 CenterTag: C23X22100CDX545000000 Period of Performance: 09/30/2023 to 09/29/2027				
1	BAA - Health and Neurodevelopmental Outcomes in Infants at Risk for (NOWS) Effects of timing and Duration of (POE) and Postnatal Management with (ESC) - Base Year Obligated Amount: \$437,576.00				437,576.00
2	BAA - Health and Neurodevelopmental Outcomes in Infants at Risk for (NOWS) Effects of timing and Duration of (POE) and Postnatal Management with (ESC) - Option Year One Amount: \$423,419.00 (Option Line Item)				0.00
3	BAA - Health and Neurodevelopmental Outcomes in Infants at Risk for (NOWS) Effects of timing and Duration of (POE) and Postnatal Management with (ESC) - Option Year Two Amount: \$426,448.00 (Option Line Item)				0.00
4	BAA - Health and Neurodevelopmental Outcomes in Infants at Risk for (NOWS) Effects of timing and Duration of (POE) and Postnatal Management with (ESC) - Option Year Three Amount: \$434,408.00 (Option Line Item)				0.00
	The total amount of award: \$1,721,851.00. The obligation for this award is shown in box 15G.				

PART I**SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

The Contractor shall furnish all facilities, materials, and personnel and shall perform all services necessary to conduct a study entitled, *“Health and Neurodevelopmental Outcomes in Infants at Risk for Neonatal Opioid Withdrawal Syndromes (NOWS): Effects of Timing and Duration of Prenatal Opioid Exposure (POE) & Postnatal Management with Eat-Sleep-Console (ESC).”*

Contract Period	Line Item	Price
30 September 2023 to 29 September 2024	BAA - Health and Neurodevelopmental Outcomes in Infants at Risk for (NOWS) Effects of timing and Duration of (POE) and Postnatal Management with (ESC) - Base Year	\$437,576.00
30 September 2024 to 29 September 2025	BAA - Health and Neurodevelopmental Outcomes in Infants at Risk for (NOWS) Effects of timing and Duration of (POE) and Postnatal Management with (ESC) - Option Year One	\$423,419.00
30 September 2025 to 29 September 2026	BAA - Health and Neurodevelopmental Outcomes in Infants at Risk for (NOWS) Effects of timing and Duration of (POE) and Postnatal Management with (ESC) - Option Year Two	\$426,448.00
30 September 2026 to 29 September 2027	BAA - Health and Neurodevelopmental Outcomes in Infants at Risk for (NOWS) Effects of timing and Duration of (POE) and Postnatal Management with (ESC) - Option Year Three	\$434,408.00
Total Estimated Amount		\$1,721,851.00

Contract Type: Cost Reimbursement (CR)

SECTION C - DESCRIPTION/SPECIFICATIONS/STATEMENT OF WORK

See Attachment A for the Statement of Work

SECTION D - PACKAGING AND MARKING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with the Government specifications below. At a minimum, all deliverables shall be marked with the contract number and contractor name.

1. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.
2. The Contractor shall scan all deliverables for viruses before submitting to the FDA.
3. Deliverables under this contract shall be prepared and packaged for shipment using best commercial practices to ensure safe and timely delivery.

SECTION E - INSPECTION AND ACCEPTANCE

All work hereunder shall be subject to review by the Government. Acceptance of the final deliverables shall be made in writing by the Contracting Officer.

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer (CO) will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <https://www.acquisition.gov/far/>.

52.246-9 Inspection of Research and Development (Short Form) (APR 1984)

Note: "Acceptable" will be defined as the Contractor's good faith effort in performing the research plan, including the budget, and will not be subject to the Government's agreement with the views, findings, and opinions of the Contractor."

SECTION F - DELIVERIES OR PERFORMANCE

F.1 PERIOD OF PERFORMANCE

Total Period of Performance: 30 September 2023 to 29 September 2027

Base Year: 30 September 2023 to 29 September 2024

Option Year One: 30 September 2024 to 29 September 2025

Option Year Two: 30 September 2025 to 29 September 2026

Option Year Tree: 30 September 2026 to 29 September 2027

F.2 PLACE OF DELIVERY

52.247-34 F.O.B. DESTINATION (NOV 1991)

All deliverables with the exception of monthly progress reports shall be delivered F.O.B. Destination, under transmittal letter, to the COR at the following address:

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993
Attention: Mary Johnson
E-mail: mary.johnson@fda.hhs.gov

F.3 DELIVERABLES

See Attachment 1, Statement of Work for deliverable schedule. In addition to the deliverables outlined herein and in the SOW, the Contractor shall submit a monthly progress report in accordance with paragraph G.5 below. All deliverables shall be sent to the COR. The final report shall be sent to the Contracting Officer and FDABAA@fda.hhs.gov. The following deliverables shall be submitted in accordance with the attached Statement of Work.

75F40123C00211

The contractor shall carry out the tasks and subtasks as outlined below, with the deliverables as indicated. For each subtasks, the deliverables are deemed acceptable with the specified assessments.

Tasks				
Task 1: Project Planning and Preparation				
		Subtasks	Deliverables	Assessment Deemed Acceptable if
	1.1	Create NOWS cohort from birth cohort	Based on inclusion and exclusion criteria, NOWS cohort created from birth cohort 2010-2023.	NOWS cohort created.
	1.2	Query dataset for maternal exposures	Sources of maternal opioid exposure established	All data or sources of opioid exposure for the study cohorts are completed, and accuracy confirmed with select samples chosen from EHR for review and validation.
	1.3	Query pharmacy records for maternal exposures	Maternal opioid exposure re: timing during pregnancy, durations, types of opioids and doses established. Milligrams morphine equivalent doses of prescription opioids during pregnancy calculated.	Prescription opioids doses data are abstracted, and conversion to MME completed.
	1.4	Query dataset for postnatal management	Postnatal management by non-pharmacologic or opioids replacement treatment confirmed	Study cohorts created based on postnatal management with non-pharmacological approach or by pharmacotherapy.
	1.5	Obtain IEP and other developmental data	All referrals for evaluations of hearing, autism, speech identified. All referrals for occupational, physical and speech therapy identified. IEP referral data obtained.	All data related to referral for evaluations or supportive therapy are complete.
	1.6	Create study cohorts	Four different study cohorts from the NOWS cohort are created based on management approaches and birth years: Pre-ESC, ESC, Pre-ESC Rx and Post-ESC Rx.	Creation of study cohort based on management approaches and birth years is complete.
Task 2: Testing and Selecting Models for Analysis				

75F40123C00211

	Subtasks		Deliverables	Assessment Deemed Acceptable if
	2.1	Generate and test match models	Generate and test different models for the matched analysis. Findings from the testing are summarized, with strengths and weaknesses of the different models identified.	Matching variables and models testing generate final list of variables and model for matching.
	2.2	Select match model to use for analysis	Select final model used for match analysis	Final model used for match analysis is selected
Task 3: Data Analysis of All Study Aims				
	Subtasks		Deliverables	Assessment Deemed Acceptable if
	3.1.1	Analysis Aim 1A All Non-Pharm vs All Rx	Analysis in the NOWS cohort, derived from the entire birth cohort from 2010-2023. Completed analysis with results that either show no differences or a difference in outcomes between non-pharmacological management compared to opioids replacement pharmacotherapy.	Analysis completed, and results regarding comparative outcomes between management approaches are found.
	3.1.2	Analysis Aim 1A ESC vs Pre-ESC Rx	Analysis that compares the in-hosp outcomes and ND outcomes between ESC-managed and opioids replacement treated infants with NOWS before 2016.	Analysis completed with findings reported.
	3.1.3	Analysis Aim 1A ESC vs Post-ESC Rx	Analysis that compares the in-hosp outcomes and ND outcomes between ESC-managed and opioids replacement treated.	Analysis completed with findings reported.
	3.2.1	Analysis Aim 1B Pilot prospective study I: Recruit/enroll	Contact children from each of the four cohorts: Pre-ESC, ESC, Pre-ESC Rx and Post-ESC to discuss study, and recruit study participants, and consent parents	Complete enrollment of 10 children from each of the four groups
	3.2.2	Analysis Aim 1B Pilot prospective study II.	Testing administered to the study participants. Draft data collection form.	Successfully complete testing in >80% of enrolled study participants.

75F40123C00211

	3.3.1	Analysis Aim 2A Sources, doses in NOWS cohorts	Determine the sources of opioid exposure in the entire NOWS cohort, and the four study cohorts.	Sources of exposure determined for all study cohorts. Analysis of doses in MME completed for prescription opioids exposed group. High MME cohort established and available for use in analysis.
	3.3.2	Analysis Aim 2 Co-exposures in NOWS cohorts	Characterize co-exposures in the NOWS cohort, the four study cohorts. Co-exposures include other substances (amphetamines, barbiturates, and illicit substances) and prescription psychoactive medications and SSRI	Co-exposures determined for all study cohorts. Co-exposures to prescription psychoactive medications determined,
	3.3.3	Analysis Aim 2: Create MME cohort	In the group with prenatal prescription opioids, review of pharmacy records to determine doses (in MME): total cumulative, range, mean, median. The top quartile MME is denoted as the high MME cohort. Characterize co-exposures in the high MME cohort. Analysis of co-exposure to prescription psychoactive medications in the high MME group.	High MME dose cohort created. Analysis of co-exposure to prescription psychoactive medications in high MME group completed
	3.4.1	Analysis Aim 3A Durations of exposures	Determine the durations of exposures (in weeks) in the NOWS cohort. Determine the distribution of exposure durations based on number of four-week periods in the NOWS cohort and the study cohorts	Durations of exposures determined for the NOWS cohort, including distribution for all study cohorts.
	3.4.1	Analysis Aim 3A Create sustained exposure cohort	Denote sustained exposure cohort: ≥ 2 four-week periods. All others are non-sustained exposure cohort.	Sustained exposure cohort created.
	3.4.2	Analysis Aim 3A Timing of exposures	Examine the timing of exposures based on the trimester(s) of exposure. Define distribution of gestational exposure in all cohorts.	Timing of exposure established and results available to be used for analysis.

75F40123C00211

	3.4.2	Analysis Aim 3A Create exposure cohorts based on timing	Designate infants with NOWS having exposure during the third trimester as the late gestational exposure cohort. Those with exposure that began in 1 st and/or 2 nd trimesters as the early gestational exposure cohort.	Exposure cohorts created based on timing of exposure.
	3.4.3	Analysis Aim 3A Outcomes in sustained cohort	Compare In-hospital and ND outcomes between sustained and non-sustained cohorts.	Analysis completed with findings confirmed and available to be reported.
	3.4.4	Analysis Aim 3A Outcomes in late cohort	Compare In-hospital and ND outcomes between exposure cohorts with different timings of exposure.	Analysis completed with findings confirmed and available to be reported.
	3.5.1	Analysis 3B Durations as a modifier of management (sustained cohort)	Subgroup analysis within the sustained and non-sustained cohorts and compare between different management approaches (All non-pharm vs All Rx)	Subgroup analysis completed with findings confirmed and available to be reported.
	3.5.2	Analysis 3B Timing as a modifier of management	Subgroup analysis within the exposure cohorts based on timing and compare between different management approaches: (All non-pharm vs All Rx)	Subgroup analysis completed with findings confirmed and available to be reported.

Task 4: : Dissemination of Study Results

	Subtasks		Deliverables	Assessment Deemed Acceptable if
	4.1	Presentation of results at meetings	Abstracts to report result of research are submitted for presentations of at national meetings of professional societies or academic medicine.	Abstracts are accepted for presentation at national meetings
	4.2	Preparation of manuscripts for publication	Manuscripts are drafted and submitted for publication in peer reviewed journals	Findings are organized as manuscripts and ready for submission for publication in peer-reviewed journals.

Task 5: Project Monitoring and Team Communication

75F40123C00211

	Subtasks		Deliverables	Assessment Deemed Acceptable if
	5.1	Monthly research team phone conferences	Virtual monthly meetings are held with participation of the entire research team to discuss research findings.	Agendas and minutes of each phone conference are maintained for documentation.
	5.2	Monthly progress reports	Study progress, challenges, and budget expenditures are summarized and submitted to FDA.	Monthly progress report of study and budget items are filed, and acknowledged
	5.3.1	First In-Person Investigators meetings	Review study progress, ensure all milestones are met, discuss problems, develop solutions, plan presentations	Meeting minutes and action items
	5.3.2	Second In-Person Investigators meetings	Review study progress, ascertain tall milestones are met, discuss problems, develop solutions, plan analysis, present & publish study results	Meeting minutes and action items
	5.3.3	Third In-Person Investigators meetings	Review study progress, ascertain tall milestones are met, discuss problems, develop solutions, plan analysis, present & publish study results	Meeting minutes and action items
	5.3.4	Fourth In-Person Investigators meetings	Review study progress, ascertain tall milestones are met, discuss problems, develop solutions, plan analysis, present & publish study results	Meeting minutes and action items
	5.3.5	Final In-Person Investigators meetings	Review study progress, ascertain tall milestones are met, discuss problems, develop solutions, plan analysis, present & publish study results	Meeting minutes and action items

75F40123C00211

WBS #	TASKS	Responsible investigator(s)	Year 1					Year 2					Year 3					Year 4				
			2023		2024			2025			2026			2027								
			Sept-Dec	Jan-Mar	Apr-Jun	Jul-Sept	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sept	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sept	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Aug				
1	Prepare and planning of study																					
1.1	Create birth cohort	LS, MK, CC, MH																				
1.2	Query dataset for maternal exposures	LS, MK, CC, MH																				
1.3	Query pharmacy records for maternal exposures	LS, MK, CC, MH																				
1.4	Query dataset for postnatal management	LS, MK, CC, MH																				
1.5	Obtain IEP and other developmental data	MK, CC, MH, CS																				
1.6	Create study cohorts	LS, MK, CC, MH																				
2	Test and finalize plans for match analysis																					
2.1	Generate and test match models	LS, MK, SP																				
2.2	Select match model to use for analysis	LS, MK, SP																				
3	Data analyses of all study aims																					
3.1.1	Analysis Aim 1A: All Non-Pharm vs All Rx	LS, MK, SP																				
3.1.2	Analysis Aim 1A: ESC vs Pre-ESC Rx	LS, MK, SP																				
3.1.3	Analysis Aim 1A: ESC vs Post-ESC Rx	LS, MK, SP																				
3.2.1	Analysis Aim 1B: Pilot prospective study: Recruit/enroll	LS, MK, SP, CS																				
3.2.2	Analysis Aim 1B: Pilot prospective study: Testing	LS, MK, SP, CS																				
3.3.1	Analysis Aim 2: Sources, doses in NOWS cohort	LS, MK, SC, SP																				
3.3.2	Analysis Aim 2: Co-exposures in NOWS cohort	LS, MK, SC, SP																				
3.5.1	Analysis Aim 3A: Durations & Create sustained exposure cohort	LS, MK, SP																				
3.5.2	Analysis Aim 3A: Timing & Create timing of exposure cohorts	LS, MK, SP																				
3.5.3	Analysis Aim 3A: Outcomes in sustained exposure cohort	LS, MK, SP																				
3.5.4	Analysis Aim 3A: Outcomes in timing of exposure cohorts	LS, MK, SP																				
3.6.1	Analysis Aim 3B: Durations as modifier of management	LS, MK, SP																				
3.6.2	Analysis Aim 3B: Timing as modifier of management	LS, MK, SP																				
4	Dissemination of study results																					
4.1	Presentation of results at meetings	LS, MK, SP, CC, MH, SC, CS																				
4.2	Preparation of manuscripts to submit for publication	LS, MK, SP, CC, MH, SC, CS																				
5	Project monitoring & study team communications																					
5.1	Monthly research team phone conferences	LS, MK, SP, CC, MH, SC, CS																				
5.2	Monthly progress reports	LS																				
5.3	In-Person Investigators meetings	LS, MK, SP, CC, MH, SC, CS																				

F.4 KICK-OFF MEETING

A kick-off meeting with Contractor and FDA representatives shall be held within one (1) month of the effective date of the contract. The kick-off meeting may be held in person, via teleconference, or via videoconference at the discretion of the COR.

F.5 52.242-15 STOP-WORK ORDER (AUG 1989) – ALTERNATE I (APR 1984)**SECTION G – CONTRACT ADMINISTRATION DATA****G.1 PAYMENT – COST REIMBURSEMENT****HHSAR 352.232-71, Electronic Submission of Payment Requests**

(a) Definitions. As used in this clause-

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(END OF CLAUSE)

FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (Jan 2022)

a. All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System

(IPP). <http://www.ipp.gov/vendors/index.htm>

b. Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract, or the clause 52.212-4

contract Terms and Conditions - Commercial Items included in commercial items contracts. The IPP website address is: <https://www.ipp.gov>

c.

1. The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the contract award for new contracts or date of modification for existing contracts.
2. Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
3. The Contractor POC will receive two emails from **IPP Customer Support**, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
4. If your company is already registered to use IPP, you will not be required to re- register.
5. If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

d. Invoices that include time and materials or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

e. Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts. At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

- Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
- Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
- Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee - amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

f. Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:

(a) list of all invoices submitted to date under the subject award, including the following:

(1) invoice number, amount, & date submitted

(2) corresponding payment amount & date received

- (b) total amount of all payments received to date under the subject contract or order
- (c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.
- g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.
- h. If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.
- i. Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.
- j. The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.
- k. Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

G.2 TRAVEL AND PER DIEM

Travel and Per Diem authorized under this contract shall be reimbursed in accordance with the FAR 31.205-46 (Travel Costs). Per Diem rates shall not exceed the Government approved rates in effect (<http://www.gsa.gov/portal/category/21287>).

Travel requirements under this contract shall be met using the most economical form of transportation available. If economy class transportation is not available, the request for payment voucher must be submitted with justification for use of higher class travel indicating dates, times, and flight numbers. All travel shall be scheduled sufficiently in advance to take advantage of offered discount rates, unless otherwise directed by the Contracting Officer.

The COR must review and approve all travel requests prior to actual travel. Supporting receipts shall be provided when invoicing for travel.

G.3 CONTRACTING OFFICER (CO)

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the project; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The contact information for the **Contracting Officer/Specialist**:

Contracting Officer

Ian Weiss
4041 Powder Mill Road
Beltsville, MD 20701
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Contract Specialist

Matthew Tran
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matthew.tran@fda.hhs.gov

The contact information for the Contractor:

Primary Contact:

Katherine Leon
Columbia University
Sponsored Projects Administration
630 West 168th Street, Box 49
New York, NY 10032
grants-office@columbia.edu
(212) 305-4191

G.4 CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following COR will represent the Government for the purpose of this contract:

Contracting Officer Representative

Mary Johnson
10903 New Hampshire Avenue

Silver Spring, MD 20993
Phone: 240-402-2647
Email: mary.johnson@fda.hhs.gov

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

G.5 MONTHLY PROGRESS REPORTS

On the fifteenth (15) day of each month for the previous calendar month, the contractor shall submit to the COR and the Contracting Officer a Technical Progress Report. Instructions for formulating Technical Progress Reports are detailed below. The Technical Progress Reports shall include project timelines and milestones summaries of product manufacturing, testing, and clinical evaluation. A Technical Progress Report will not be required for the period in which the Final Report is due. The Contractor shall submit two copies of the Technical Progress Report electronically via e-mail to the CO and COR. Any attachments to the e-mail report shall be submitted in Microsoft Word, Microsoft Excel, and/or Adobe Acrobat PDF files. Such reports shall include the following information:

- a. Title page containing: Technical Progress Report, the contract number and title, the period of performance or milestone being reported, the Contractor's name, address, and other contact information, the author(s), and the date of submission;
- b. Introduction/Background: An introduction covering the purpose and scope of the contract effort;
- c. Progress: The report shall detail, document and summarize the results of work performed, test results, milestones achieved during the period covered and cumulative milestones achieved. Must also include a summary of work planned for the next two (2) reporting periods on a rolling basis;
- d. Issues: Issues resolved, new issues and outstanding issues are enumerated with options and recommendation for resolution. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if progress activity is delinquent, and what corrective steps are planned. Revised timelines are to be included.
- e. Invoices: Summary of any invoices submitted during the reporting period.
- f. Action Items: Summary table of activities or tasks to be accomplished by certain date and by whom.
- g. Distribution list: A list of persons receiving the Technical Report

- h. Attachments: Results on the project are provided as attachments

The monthly progress reports shall be delivered via email to the Contract Specialist (CS) and the Contracting Officer's Representative (COR) at the following email addresses:

CS: matthew.tran@fda.hhs.gov

COR: mary.johnson@fda.hhs.gov

G.6 FINAL REPORT

By the expiration date of the contract, the Contractor shall submit a 508 compliant Final Report that shall detail, document, and summarize the results of the entire contract work. The report shall explain comprehensively the results achieved. A draft Final Report will be submitted to the CO and COR for review and comments, then the Final Report original, copies, and an electronic file shall be submitted to the CO and COR for distribution to the Program office. Included in the final report shall be an executive summary (in plain language) within the report to summarize the results of the contract and include outcomes with possible impacts on FDA mission. The final report must have a table of contents and page numbers. Preferred Font: Calibri or Times New Roman and Size 11. The final report shall also be submitted to: FDABAA@fda.hhs.gov.

G.7 HHSAR 352.237-75 KEY PERSONNEL (DEC 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The Key Personnel under this contract are:

Lena S. Sun – Principal Investigator
Sandra Comer, PhD – Co-Principal Investigator
Jacquelin Narula – Project Research Coordinator

G.8 REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in FDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The email address is

HHStips@oig.hhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
Attn: HOTLINE
330 Independence Avenue, S.W.
Washington, D.C. 20201

SECTION H - SPECIAL CONTRACT REQUIREMENTS

H.1 DISSEMINATION OF CONTRACT INFORMATION

FDA considers the sharing of research resources developed through FDA-sponsored research an important means to enhance the value and further the advancement of research. When research resources have been developed with FDA funds and the associated research findings published, those findings must be made readily available to the scientific community.

Upon acceptance for publication, scientific researchers must submit the author's final manuscript of the peer-reviewed scientific publication resulting from research supported in whole or in part with FDA funds to the NIH National Library of Medicine's (NLM) PubMed Central (PMC). FDA defines the author's final manuscript as the final version accepted for journal publication, which includes all modifications from the publishing peer review process. The PMC archive is the designated repository for these manuscripts for use by the public, health care providers, educators, scientists, and FDA. Please see the *FDA Public Access Policy*.

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted for FDA COR review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. "Publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information.

The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. Misrepresenting contract results or releasing information that is injurious to the integrity of FDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the COR has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

The Contractor is responsible for ensuring compliance with all export control laws and regulations that maybe applicable to the export of and foreign access to their proposed technologies. Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CFR Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CFR Parts 730-774).

H.2 CONFLICT OF INTEREST

As a regulatory agency charged with protection of public health, the Food and Drug Administration (FDA) must maintain public confidence in the integrity of its decisions. The FDA has policies and procedures that safeguard against actual and apparent conflict of interest on the part of its employees. In contracting for review and evaluation of scientific data and information submitted to the agency, it is critical that the FDA be assured that there is no actual or apparent conflict of interest on the part of the individual contractor. Offers performing work under this contract must assure the protection of information and data they receive under this contract from unauthorized use or disclosure, and must avoid actions that would cause a reasonable person to question the impartiality of the contractor.

(a)Purpose. The purpose of this clause is to ensure that the contractor and its subcontractors:

(1) Are not biased because of their financial, contractual, organizational, or other interests which relate to the work under this contract, and

(2) Do not obtain any unfair competitive advantage over other parties by virtue of their performance of this contract.

(b)Scope. The restrictions described herein shall apply to performance or participation by the contractor, its parents, affiliates, divisions and subsidiaries, and successors in interest (hereinafter collectively referred to as "contractor") in the activities covered by this clause as a prime contractor, subcontractor, co-sponsor, joint venturer, consultant, or in any similar capacity. For the purpose of this clause, affiliation occurs when a business concern is controlled by or has the power to control another or when a third party has the power to control both.

(c)Warrant and Disclosure. The warrant and disclosure requirements of this paragraph apply with full force to both the contractor and all subcontractors. The contractor warrants that, to the best of the contractor's knowledge and belief, there are no relevant facts or circumstances which would give rise to an organizational conflict of interest, as defined in FAR Subpart 9.5, and that the contractor has disclosed all relevant information regarding any actual or potential conflict. The contractor agrees it shall make an immediate and full disclosure, in writing, to the Contracting Officer of any potential or actual organizational conflict of interest or the existence of any facts that may cause a reasonably prudent person to question the contractor's impartiality because of the appearance or existence of bias or an unfair competitive advantage. Such disclosure shall include a description of the actions the contractor has taken or proposes to take in order to avoid, neutralize, or mitigate any resulting conflict of interest.

(d)Remedies. The Contracting Officer may terminate this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid, neutralize or mitigate an actual or apparent organizational conflict of interest. If the contractor fails to disclose facts pertaining to the existence of a potential or actual organizational conflict of interest or misrepresents relevant information to the Contracting Officer, the Government may terminate the contract for default, suspend or debar the contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

(e)Subcontracts. The contractor shall include a clause substantially similar to this clause, including paragraphs (f) and (g), in any subcontract or consultant agreement at any tier expected to exceed the simplified acquisition threshold. The terms “contract,” “contractor,” and “Contracting Officer” shall be appropriately modified to preserve the Government's rights.

(f)Prime Contractor Responsibilities. The contractor shall obtain from its subcontractors or consultants the disclosure required in FAR Part 9.507-1, and shall determine in writing whether the interests disclosed present an actual, or significant potential for, an organizational conflict of interest. The contractor shall identify and avoid, neutralize, or mitigate any subcontractor organizational conflict prior to award of the contract to the satisfaction of the Contracting Officer. If the subcontractor's organizational conflict cannot be avoided, neutralized, or mitigated, the contractor must obtain the written approval of the Contracting Officer prior to entering into the subcontract. If the contractor becomes aware of a subcontractor's potential or actual organizational conflict of interest after contract award, the contractor agrees that the Contractor may be required to eliminate the subcontractor from its team, at the contractor's own risk.

(g)Waiver. The parties recognize that this clause has potential effects which will survive the performance of this contract and that it is impossible to foresee each circumstance to which it might be applied in the future. Accordingly, the contractor may at any time seek a waiver from the Head of the Contracting Activity by submitting such waiver request to the Contracting Officer, including a full written description of the requested waiver and the reasons in support thereof.

H.3 REQUIREMENTS FOR CLINICAL TRIALS

As part of 21st Century Cures, HHS is required to consult with relevant Federal agencies, including FDA, and other stakeholders within 90 days of enactment to receive recommendations with respect to enhancements to the ClinicalTrials.gov databank. These recommendations are to address the usability, functionality, and search capability of the databank. NIH has confirmed that it is the lead agency for this provision and has indicated that the recommendations should be focused on the outward facing aspects of ClinicalTrials.gov, as opposed to items related to entering information or new data elements to be collected.

FDA's Office of Good Clinical Practice (OGCP) is requesting input to help NIH address this 21st Century Cures requirement. Because many different groups at FDA (e.g., review divisions, compliance offices) use ClinicalTrials.gov for a variety of purposes, we ask that you share this request broadly within your organization. Please focus on suggestions related to enhancements of the usability and search functions of ClinicalTrials.gov which may improve or augment work at FDA. Suggestions may include, but are not limited to, items such as the ease of use of the main ClinicalTrials.gov webpage, improved search capabilities, or data output formats. Recommendations related to enhancements which may be useful for FDA stakeholders, such as patients searching for clinical trials, are also being requested.

All research under this BAA must address the involvement of human subjects and protections from research risk related to their participation in the proposed research plan and comply with 32 CFR 219, 10 U.S.C. 980, and, as applicable, 21 CFR Parts 11, 50, 54, 56, 312) (45 CFR Part 46) and the ICH as well as other applicable federal and state regulations. HHS Policy also requires that women and members of minority groups and their subpopulations: children and the elderly (pediatric and geriatric) must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects or the purpose of the research. The HHS policy on studies that involved human subjects can be accessible through the HHS website: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

Research Projects involving humans and/or human specimens can only be initiated with written approval by the FDA Contracting Officer. The Food and Drug Administration Amendments Act of 2007 (FDAAA) contains provisions that expand the current database known as ClinicalTrials.gov to include additional requirements for individuals and entities who are involved in conducting clinical trials that involve products regulated by FDA or that are funded by the Department of Health and Human Services (HHS), including FDA. These additional requirements include mandatory registration of certain types of clinical trials, as well as reporting of results for certain trials ("applicable trials") for inclusion in the ClinicalTrials.gov database. More detailed information on the definition of "applicable clinical trial" and the registry and results reporting requirements can be found at <https://clinicaltrials.gov/ct2/manage-recs/fdaaa>. FDAAA also added new requirements concerning clinical trials supported by grants and contracts from HHS, including FDA. Under these provisions, any contract or progress report forms required under a contract from any part of HHS, including FDA, must include a certification that the "responsible party" has submitted all required information to the ClinicalTrials.gov registry database. The responsible party is the term used in Title VIII of FDAAA (PL 110-85) to refer the entity or individual responsible for meeting FDAAA's requirement. Under BAA contracts, the Contractor assumes the responsibility, and will register a clinical investigation and submit Clinical Trial Information to the Clinical Trial Registry Data Bank if determined to be an applicable clinical trial. In case where the existing policy at the contractor's institution requires a registration at the Clinical Trial Registry, the contractor shall provide a letter that clearly states the policy and the extent of responsibility within 30 days of the Award/Contract. This letter should be signed by the contractor and cosigned by the institutional official, and sent to the COR and the Contracting Officer (CO). More detailed information on the definition of "applicable clinical trial" and the "responsible party" can be found at <http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>. There are also provisions regarding when agencies within HHS, including FDA, are required to verify compliance with the database requirements before releasing funding to contractors.

H.4 CONTRACTOR PERFORMANCE EVALUATION(S)

In accordance with Federal Acquisition Regulation (FAR) 42.15, FDA will complete annual and final contractor performance evaluations. Annual evaluations will be prepared to coincide with the anniversary date of the contract. Additional interim performance evaluations may be prepared at Contracting Officer discretion, as necessary. Final performance evaluations will be completed upon contract expiration.

FDA will utilize the Contractor Performance Assessment Reporting System (CPARS) in order to execute annual and final contractor performance evaluations. CPARS is a secure Internet website located at <http://www.cpars.gov/>. FDA will register the contractor in CPARS upon receipt of the name and email address of two (2) individuals who will be responsible for serving as the Contractor's primary and alternate CPARS contacts. Once FDA registers the contractor in CPARS, the Contractor will receive an automated CPARS email message which contains User IDs and instructions for creating a password.

Once a performance evaluation is issued, the Contractor's primary and alternate CPARS contact will receive an email instructing them to logon to CPARS in order to review the performance evaluation. The Contractor has 15 days from the date of performance evaluation issuance in which to review the evaluation. If the Contractor is in agreement with the performance evaluation outcome, the evaluation becomes final. Should the Contractor be in disagreement with the performance evaluation outcome, rebuttal comments must be submitted via the CPARS within 15 days from date the evaluation was issued by FDA. Any disagreement between the Contracting Officer and the Contractor will be referred to a contracting official one level above the Contracting Officer, whose decision will be final.

Copies of each performance evaluation and contractor responses, if any, will be retained as part of the official contract file and will be used to support future award decisions. Evaluations will also be stored for a 3 year period in the Past Performance Information Retrieval System (PPIRS) at www.ppirs.gov.

Contractors may obtain CPARS training material and register for on-line training at <http://www.cpars.gov/allapps/cpcbtdlf.htm>. There is no fee for registration or use of the CPARS.

H.5 508 STANDARD REQUIREMENTS:

HHSAR 352.239-74 Electronic and Information Technology Accessibility (DEC 2015)

(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.

(b) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see [FAR 2.101](#)) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility

standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(c) The Section 508 accessibility standards applicable to this contract are:

Software applications and operating systems

Web-based intranet and internet information and applications

1194.31 Functional performance criteria

1194.41 Information, documentation, and support

(d) In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS website: (<http://www.hhs.gov/web/508>). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(e) If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <http://www.hhs.gov/web/508>. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

H.6 352.270-4b Protection of Human Subjects (December 18, 2015)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.

(c) Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP website at: <http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf> - PDF).

(d) If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

H.6 Restriction on Use of Human Subjects (December 18, 2015)

Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) registered with OHRP. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

H.7 Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required (December 18, 2015)

(a) The Contractor agrees to protect the rights and welfare of human subjects involved in research under this contract by complying with 45 CFR Part 46 and the clause at [HHSAR 352.270-4b](#).

(b) Initial proof of compliance with 45 CFR Part 46 shall consist of:

- (1) A copy of a current Federal-wide Assurance on file with OHRP. The copy of a current Federal-wide Assurance shall be included with the Contractor's proposal;
- (2) A letter from the Contractor's local IRB (the Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance) stating that it has reviewed and approved the proposed research protocol. The letter from the local IRB shall be submitted to the Contracting Office; and
- (3) A copy of a letter from the RIHSC stating that it or its designee has reviewed and approved the proposed research protocol. This shall be submitted to the Contracting Officer within three business days of its issuance.

The Contractor shall not advertise for, recruit, or enroll human subjects, or otherwise commence any research involving human subjects under this contract, until RIHSC has reviewed and approved its research. The Contractor may commence other limited aspects of contract performance prior to receiving RIHSC or its designee approval of its proposed research protocol. Research involving human subjects may commence immediately upon the Contractor's receipt of RIHSC or its designee approval; however, the Contractor shall submit a copy of RIHSC's or its designee's letter of approval to the Contracting Officer within three business days of its receipt.

Failure to obtain RIHSC or its designee approval of proposed research protocols may result in the termination of this contract.

(c) The Contractor further agrees that:

- (1) The Contractor will provide a letter from RIHSC, at least annually, stating that RIHSC or its designee has reviewed and approved the research protocols for research performed under this contract. This shall be submitted to the Contracting Officer for inclusion in the contract file.
- (2) The Contractor will submit all proposed modifications and amendments to research protocols for research performed under this contract to RIHSC for review and approval. Modifications and amendments include, but are not limited, to changes to consent forms and advertising materials, and the addition or deletion of investigators. Changes may be instituted immediately after the Contractor has received both the local IRB and RIHSC or its designee approval (except when necessary to eliminate apparent immediate hazards to the subject); however the Contractor shall submit a copy of the letter evidencing RIHSC's or its designee's approval of the proposed changes to the Contracting Officer within three business days of its receipt.

H.8 Human Subjects Protection Review

For research exempt from the requirements of 45 CFR Part 46:

- (a) The Contractor will submit to FDA a letter from their IRB or human subject protection entity that the proposed research is exempt (see 45 CFR 46.104).

(b) In accordance with SMG 9001.4, FDA will follow its procedures for exempt research determination. Data collection from human subjects cannot commence under this contract until the FDA COR provides the Contractor with the outcome of the FDA determination.

For nonexempt human subjects research:

(a) The Contractor agrees to protect the rights and welfare of human subjects involved in research under this contract by complying with 45 CFR Part 46 and the clause at HHSAR 352.270-4b.

(b) Initial proof of compliance with 45 CFR Part 46 shall consist of:

(1) A copy of a current Federal-wide Assurance on file with OHRP (<https://www.hhs.gov/ohrp/federalwide-assurances-fwass.html>). The copy of a current Federal-wide Assurance shall be included with the Contractor's proposal;

(2) A letter from the Contractor's local IRB (the Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance) stating that it has reviewed and approved the proposed research protocol. The letter from the local IRB shall be submitted to the Contracting Officer Representative (COR).

(3) In accordance with SMG 9001.4, the FDA will determine if FDA is considered engaged in the research for purposes of 45 CFR part 46. Data collection from human subjects cannot commence under this contract until the FDA COR provides the Contractor with the outcome of the FDA determination. When that determination is made, the FDA will confirm the extent to which the terms of "352.270-11 Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required" apply.

P A R T I I**SECTION I - CONTRACT CLAUSES****FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)**

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the CO will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <https://www.acquisition.gov/far/>.

FAR 52.202-1	Definitions (JUN 2020)
FAR 52.203-3	Gratuities (APR 1984)
FAR 52.203-5	Covenant Against Contingent Fees (MAY 2014)
FAR 52.203-6	Restrictions on Subcontractor Sales to the Government (JUN 2020)
FAR 52.203-7	Anti-Kickback Procedures (JUN 2020)
FAR 52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (MAY 2014)
FAR 52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (MAY 2014)
FAR 52.203-12	Limitation on Payment to Influence Certain Federal Transactions (JUN 2020)
FAR 52.203-14	Display of Hotline Poster(s) (NOV 2021)
FAR 52.203-17	Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights (JUN 2020)
FAR 52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017)
FAR 52.204-4	Printed or Copied Double-Sided on Recycled Paper (MAY 2011)
FAR 52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020)
FAR 52.204-13	System for Award Management Maintenance (OCT 2018)
FAR 52.204-14	Service Contract Reporting Requirements (OCT 2016)

FAR 52.204-18 Commercial and Government Entity Code Maintenance (AUG 2020)

FAR 52.204-19 Incorporation by Reference of Representation and Certifications (DEC 2014)

FAR 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (NOV 2021)

FAR 52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (NOV 2021)

FAR 52.204-27 Prohibition on a ByteDance Covered Application (JUN 2023)

FAR 52.209-6 Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (NOV 2021)

FAR 52.209-9 Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018)

FAR 52.209-10 Prohibition on Contracting with Inverted Domestic Corporations (NOV 2015)

FAR 52.215-2 Audit and Records - Negotiation (JUN 2020) – Alternate II (AUG 2016)

FAR 52.215-8 Order of Precedence - Uniform Contract Format (OCT 1997)

FAR 52.216-7 Allowable Cost and Payment (AUG 2018) - Alternate II (AUG 2012)

FAR 52.216-11 Cost Contract – No Fee (APR 1984) - Alternate I (APR 1984)

FAR 52.216-15 Predetermined Indirect Cost Rates (APR 1998)

FAR 52.217-8 Option to Extend Services (NOV 1999)

FAR 52.217-9 Option to Extend the Term of the Contract (MAR 2000)

FAR 52.219-8 Utilization of Small Business Concerns (OCT 2018)

FAR 52.219-9 Small Business Subcontracting Plan (NOV 2021) - Alternate II (NOV 2016)

FAR 52.219-16 Liquidated Damages—Subcontracting Plan (JAN 1999)

FAR 52.219-28 Post-Award Small Business Program Re-representation (SEP 2021)

FAR 52.222-2 Payment of Overtime Premiums (JUL 1990)

The use of overtime is authorized under this contract if the overtime premium does not exceed \$125.00.

- FAR 52.222-3 Convict Labor (JUN 2003)
- FAR 52.222-21 Prohibition of Segregated Facilities (APR 2015)
- FAR 52.222-26 Equal Opportunity (SEP 2016)
- FAR 52.222-35 Equal Opportunity for Veterans (JUN 2020)
- FAR 52.222-36 Equal Opportunity for Workers with Disabilities (JUN 2020)
- FAR 52.222-37 Employment Reports on Veterans, (JUN 2020)
- FAR 52.222-40 Notification of Employee Rights Under the National Labor Relations Act (DEC 2010)
- FAR 52.222-50 Combating Trafficking in Persons (NOV 2021)
- FAR 52.222-54 Employment Eligibility Verification (NOV 2021)
- FAR 52.223-6 Drug-Free Workplace (MAY 2001)
- FAR 52.223-18 Encouraging Contractor Policies to Ban Text messaging While Driving (JUN 2020)
- FAR 52.225-1 Buy American Act—Supplies (NOV 2021)
- FAR 52.225-13 Restrictions on Certain Foreign Purchases (FEB 2021)
- FAR 52.227-1 Authorization and Consent (JUN 2020) – Alternate I (APR 1984)
- FAR 52.227-2 Notice and Assistance Regarding Patent and Copyright Infringement (JUN 2020)
- FAR 52.227-11 Patent Rights—Ownership by the Contractor (MAY 2014)
- FAR 52.227-14 Rights in Data - General (MAY 2014) - Alternate IV (DEC 2007)
- FAR 52.227-16 Additional Data Requirements (JUN 1987)
- FAR 52.228-7 Insurance - Liability to Third Persons (MAR 1996)
- FAR 52.232-20 Limitation of Cost (APR 1984)

FAR 52.232-23 Assignment of Claims (MAY 2014)

FAR 52.232-25 Prompt Payment (Jan 2017) - Alternate I (FEB 2002)

FAR 52.232-33 Payment by Electronic Funds Transfer-System for Award Management (OCT 2018)

FAR 52.232-39 Unenforceability of Unauthorized Obligations (JUN 2013)

FAR 52.232-40 Providing Accelerated Payments to Small Business Subcontractors (NOV 2021)

FAR 52.233-1 Disputes (MAY 2014)

FAR 52.233-3 Protest after Award (AUG 1996) - Alternate I (JUN 1985)

FAR 52.233-4 Applicable Law for Breach of Contract Claim (OCT 2004)

FAR 52.242-1 Notice of Intent to Disallow Costs (APR 1984)

FAR 52.242-3 Penalties for Unallowable Costs (SEP 2021)

FAR 52.242-13 Bankruptcy (JUL 1995)

FAR 52.243-2 Changes - Cost-Reimbursement (AUG 1987) - Alternate V (APR 1984)

FAR 52.244-2 Subcontracts (JUN 2020) – Alternate I (JUN 2020)

FAR 52.244-5 Competition in Subcontracting (DEC 1996)

FAR 52.244-6 Subcontracts for Commercial Items (JAN 2022)

FAR 52.245-1 Government Property (SEP 2021) - Alternate II (APR 2012)
Title to property purchased with an acquisition cost of \$5,000 or more shall vest in the Government, unless otherwise noted in writing by the Contracting Officer.

FAR 52.246-25 Limitation of Liability - Services (FEB 1997)

FAR 52.249-5 Termination for Convenience of the Government (Educational and Other Nonprofit Institutions) (AUG 2016)

FAR 52.249-14 Excusable Delays (APR 1984)

FAR 52.253-1 Computer Generated Forms (JAN 1991)

HHSAR 352.203-70	Anti-Lobbying (DEC 2015)
HHSAR 352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations (DEC 2015)
HHSAR 352.223-70	Safety and Health (DEC 2015)
HHSAR 352.224-70	Privacy Act (DEC 2015)
HHSAR 352.224-71	Confidential Information (DEC 2015)
HHSAR 352.227-70	Publications and Publicity (DEC 2015)
HHSAR 352.231-70	Salary Rate Limitation (DEC 2015)

HHS FAR Class Deviations

FAR 52.232-40 PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS (NOV 2021) [(DEVIATION APR 2020)]

(a)[(1) **In accordance with 31 U.S.C. 3903 and 10 U.S.C. 2307, u**], Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract **[in accordance with the accelerated payment date established]**, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, **[with a goal of 15 days]** after receipt of a proper invoice and all other required documentation from the small business subcontractor **[if a specific payment date is not established by contract.**

(2) The Contractor agrees to make such payments to its small business subcontractors without any further consideration from or fees charged to the subcontractor].

(b) The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.

(c) Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of clause)

PART III

SECTION J - LIST OF ATTACHMENTS

- A. Statement of Work
- B. Rate Agreement
- C. Small Business Subcontracting Plan